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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/672,265 | 09/28/2000 | Michael Bott | BMID9975US | 8449 |

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 05/10/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/672,265

Applicant(s)

BOTT ET AL.

Examiner

Charles L. Patterson, Jr.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/22/01, 5/7/01, and 3/28/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) 27-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1652

Applicant's election without traverse of claims 16-26 in Paper No. 13 is acknowledged. Claims 27-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

The disclosure is objected to because of the following informalities:

In the last sentence of page 7 it is stated that genes "homologous to *E. coli* citX are shown by light grey shading. Figure 2 does not contain any "light grey shading",

Appropriate correction is required.

Claims 17, 18, 20-23, 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

✓ Claim 17 is indefinite in the recitation of "and/or". It is not clear whether the cumulative or alternative is desired.

✓ Claims 18, 21, 23 and 25 are incorrect in that the genus and species should be italicized or underlined.

✓ Claim 20 is confusing in the recitation of the parentheses around "A" and "I". It is not clear what the difference is meant to be between these amino acids and the others listed. While G, A, R, L, D, I and V are understood to be the one letter abbreviations for amino acid, "X" is undefined.

✓ Claim 22 is confusing in the recitation of "are derived from a microorganism that is specific for the isolated protein with citrate lyase activity". What is "the isolated protein" referring to? It is not understood what is being required here. Supposedly any microorganism that has

Art Unit: 1652

citrate lyase activity will have an "isolated protein" with citrate lyase activity".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the genes citC, citD, citE, citF, citX and cit G in that order transformed into *E. coli*, does not reasonably provide enablement for the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification apparently teaches that when the genes citC, citD, citE, citF, citX and citG in that order are placed into an expression vector, the citC, citD, citE, citF and citG genes being obtained from *Klebsiella pneumoniae* and the citX obtained from *E. coli*, and this vector transformed into *E. coli*, an active citrate lyase was produced. The instant claims are drawn to "at least six genes", with the genes not being specified and "a DNA fragment obtainable from *E. coli*" without specifying what that fragment is. In addition claim 21 recites *Haemophilus influenzae* and *Leuconostoc mesenteroides* and it has not been shown that the genes from these organisms will be operable in the instant invention. One of ordinary skill in the art would not know from reading this specification that claims of this scope would be operable to produce an active citrate lyase enzyme.

Art Unit: 1652

Also, it is not known whether claim 20 is enabled or not because, while it is stated on page 3 that "it is preferred that one of the genes represents a DNA fragment which codes for a protein containing the motif F(A)-R-L-X-D-L(I)-D-V", it is not stated which if any of the genes code for this motif. The significance of this is also not explained.

What applicants apparently discovered was that if the citX gene from *E. coli* was placed between citF and citG, an active enzyme could be produced in *E. coli*. The instant claims are drawn to embodiments much broader than this and it is maintained that the claims should be properly limited to what was invented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-17 and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Bott, et al. (U). The instant reference teaches a plasmid (pES3) that contains at least six genes and an inducible promoter. The presence of the promoter is discussed in the paragraph spanning columns 1 and 2

Art Unit: 1652

of page 534. Claims 18-21 are not rejected because the reference does not teach any DNA fragment between citF and citG. A copy of this references is not being sent because the authors are the same as the inventors of the instant application.

Claims 16-22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Blattner, et al. (V) or Oshima, et al. (W). The instant references teach a 100% identity with SEQ ID NO:3, which is the sequence containing the genes citC, citD, citE, citF, citX and citG in that order. Attached to Blattner, et al. is the sequence search showing the match. It would have been obvious and well within the skill level of one of ordinary skill in the art to place the DNA into a plasmid with an inducible promoter, the motivation being to produce the nucleic acid and the corresponding protein. The plasmid would have inherently produced citrate lyase, absent convincing proof to the contrary. Claims 23-23 are not rejected because *Klebsiella* is not taught by the reference.

The examiner does not understand why the genome of *E. coli* contains the genes for citC, citD, citE, citF, citX and citG in that order since according to the specification the citC, citD, citE, citF and citG genes were derived from *Klebsiella pneumoniae*. Perhaps applicants have submitted the wrong sequence for the instant invention.

It is noted for the record that applicants cannot rely on the priority document to overcome this rejection as a translation is not of record.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose

• Art Unit: 1652

telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
May 9, 2002